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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,704	02/16/2006	Karlheinz Bortlik	112701-706	4852
29157	7590	05/28/2009	EXAMINER	
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			MI, QIUWEN	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/568,704

Applicant(s)

BORTLIK ET AL.

Examiner

QIUWEN MI

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/09 has been entered.

Applicant's amendment in the reply filed on 1/28/09 is acknowledged. Claim 13 is cancelled. Claims 1-12, 14, and 15 are pending. Claims 6-8, 12, 14, and 15 are withdrawn as they are directed toward a non-elected invention group. **Claims 1-5, and 9-11 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Objections

Claims 1-5, and 9-11 are objected to because of the following informalities:

Claims 1 (line 1), 9 (line 3), 10 (line 3), and 11 (line 2) recite "Natural lycopene concentrate ...", which is grammatically improper. Applicant is suggested to recite "A natural lycopene concentrate ..." instead.

Claims 2-5 recite "Concentrate according to Claim 1..." (line 1), which is grammatically improper. Applicant is suggested to recite "The concentrate according to Claim 1..." instead.

All other cited claims depend directly or indirectly from objected claims and are, therefore, also, objected for the reasons set forth above.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 9, 10, and 11 recite "natural lycopene concentrate that contains no solvent...", Although on page 7 of the specification (2nd paragraph) from the bottom, it mentions "without using a solvent", However, on page 7 of the specification, example 1 explicitly recites "50 kg of tomato puree at pH 4.3 are mixed with 100 kg of demineralized water in a batch". It is noted that water is a solvent, thus Applicant does not have support for "contains no solvent". Especially considering that a natural lycopene concentrate inherently contains water, which is a solvent by itself. Maybe Applicant meant to say "contains no organic solvent". Therefore, Applicant fails to provide support regarding the description of "contains no solvent". Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "a natural lycopene concentrate that contains no solvent" in the invention. Thus, the subject matter of "contains no solvent" is a new matter that needs to be cancelled.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (line 1), 9 (line 3), 10 (line 3), and 11 (line 2) recite “natural lycopene concentrate”. The term “natural lycopene concentrate” in claims 1, and 9-11 is a relative term which renders the claim indefinite. The term “natural” is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably appraisal of the scope of the invention. Thus, the metes and bounds of claims 1, and 9-11 are rendered uncertain by the phrase “natural lycopene concentrate” in claims 1, and 9-11 because “natural” could be a relative term.

Claims below recite the following limitations in the claims, and there are insufficient antecedent basis for these limitations in the claims:

“the use of a solvent” in claim 1, line 6; claim 9, line 9; claim 10, line 8; and claim 11, line 7.

“the ageing” in claim 9, line 1; claim 10, line 2. “The ageing” of the skin includes wrinkles, pigmentation, dullness, itching, or dryness etc, and it is not clear which sign of ageing Applicant is referring to.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, and 2 are rejected under 35 USC § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawaragi et al (US 5,871, 574).

Kawaragi et al teach the tomato concentrates contain richly such insoluble solid matters as pulp, polysaccharides and proteins and such soluble matters as sugars, acids (thus organic acids), and aromatic substances (col 1, lines 40-45). Kawaragi et al also teach 1,300 kg of tomato fruit (thus a lycopene-containing material) was washed and mashed in the usual ways, and after heated to 65 degree. C., squeezed by a finisher provided with a 0.5 mm screen (thus a solid-liquid separation) to obtain 1,150 kg of tomato juice (thus the concentrate is isolated from fibers and other insoluble compounds, thus is water-soluble at room temperature, thus a liquid) with a Brix degree of 5 and a lycopene content of 12 mg % (thus no solvent was used up to this point) (col 11, Example 14, lines 12-20). Kawaragi et al also teach the present invention, therefore, is intended to offer a method for producing, at high efficiency and by simple means, a tomato pigment of high purity and good color tone, which pigment has lycopene as its main component and is useful as a natural coloring matter for foods (thus a composition or dietary supplement which can be ingested orally in order to optimize the absorption of lycopene so as to induce photoprotection and thus slow the ageing of skin) or as a natural pigment for cosmetics such as rouge (thus slowing the ageing of the skin and/or combat skin damage which may be caused by exposure to ultraviolet light) or pharmaceutical products of non-official grade (col 2, lines 1-10). Kawaragi et al further teach said retentate contains an enriched lycopene complex which is very low in content of impurities, for example, high-molecular weight substances such as protein and low-molecular weight substances such as sugars, organic acids and amino-acids, but its color tone is not always satisfactory. Kawaragi et al further teach these methods, although capable of

removing the water-soluble impurities originating in feedstock tomato, is unable to eliminate the fat-soluble substances (thus a lipid compound) coexisting with lycopene, such as other carotenoid substances (thus a lipid compound) (col 4, lines 60-65)..

As discussed above, the cited reference discloses a natural lycopene concentrate. Although the cited reference does not explicitly teach the claimed amount of protein, polysaccharide, organic acid, and lipid compounds, since the cited reference Kawaragi et al use the same plant material tomato as the specification (see page 7, Example 1) to start with, and use no solvent up to the above mentioned step, thus the lycopene concentrate would inherently contain the claimed amount of each component. Consequently, the claimed composition appears to be anticipated by the references.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced method is likely to inherently possess the same characteristics of the claimed method particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed method would have been obvious to those of ordinary skill in the art with the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the art rejection above, please note that Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' method differs and, if so, to what extent, from that of discussed references. Therefore, with the showing

of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaragi et al as applied to claims 1 and 2 above, and further in view of Hamm et al (Hamm et al, Vitamin C content of thirty-six varieties of tomatoes, FASEB Journal, (1993) Vol. 7, No. 3-4, pp. A742), and Breton (US 2003/0027772).

The teachings of Kawaragi et al are set forth above and applied as before.

The teachings of Kawaragi et al do not specifically teach the claimed amount of lycopene in the concentrate, a cosmetic, a food composition comprising lycopene, lycopene concentrate contains vitamin E or vitamin C, or a dietary supplement containing doses of 0.001 to 100% of a concentrate comprising natural lycopene concentrate.

As evidenced by Hamm et al, tomato contains vitamin C (see Title).

Breton teaches a composition in soft capsules for chronological ageing and photo-ageing of the skin (see Abstract) comprising 40 mg soya oil, 85 mg wheat germ oil, 25 mg soya

lecithins, 3 mg natural tocopherols, 50 mg vitamin C, 5 mg lycopene, and 25 mg genistein (thus the totally lycopene percentage is $5 \text{ mg}/233 \text{ mg} = 2.1\%$) ([0081], Example 2).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use a cosmetic, a food, or a dietary supplement containing natural lycopene since Kawaragi et al teach lycopene is useful as a natural coloring matter for foods or as a natural pigment for cosmetics such as rouge or pharmaceutical products of non-official grade. It would also have been obvious for one of ordinary skill in the art to use a dietary supplement containing 2.1% natural lycopene from Breton since Breton teaches a composition in soft capsules for chronological ageing and photo-ageing of the skin containing 2.1% of lycopene, which falls into the claimed range of 0.001 to 100% of lycopene.

Since both of the inventions yielded beneficial results for using lycopene, one of ordinary skill in the art would have been motivated to make the modifications to combine the two teachings together.

Regarding the claimed amount of lycopene in the concentrate, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454,

456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of lycopene, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655